

Smoking cessation initiated during hospital stay for patients with coronary artery disease: a randomized controlled trial

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∞ See related commentary by Rigotti, page 1283

ABSTRACT

Background: Programs for smoking cessation for cardiac patients are underused in Canada. We examined the efficacy of an intervention for smoking cessation for patients admitted to hospital for coronary artery bypass graft (CABG) or because of acute myocardial infarction (MI).

Methods: Nurses randomly assigned 276 sequential patients admitted because of acute MI or for CABG who met the inclusion criteria. Participants received an intensive or minimal smoking-cessation intervention. The minimal intervention included advice from physicians and nurses and 2 pamphlets. The intensive intervention included the minimal intervention plus 60 minutes of bedside counselling, take-home materials and 7 nurse-initiated counselling calls for 2 months after discharge. The outcomes were point prevalence of abstinence at 3, 6 and 12 months after discharge.

Results: The 12-month self-reported rate of abstinence was 62% among patients in the intensive group and 46% among those in the minimal group (odds ratio [OR] 2.0, 95% confidence interval [CI] 1.2–3.1). Abstinence was confirmed for 54% of patients in the intensive group and 35% in the minimal group (OR 2.0, 95% CI 1.3–3.6). Abstinence was significantly lower among those who used pharmacotherapy than among those who did not ($p < 0.001$). Continuous 12-month abstinence was 57% in the intensive group and 39% in the minimal group ($p < 0.01$). It was significantly higher among patients admitted for CABG than among those admitted because of acute MI ($p < 0.05$).

Interpretation: Providing intensive programs for smoking cessation for patients admitted for CABG or because of acute MI could have a major impact on health and health care costs.

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smoking-cessation measures among those with coronary artery disease results in greater reductions in mortality risk^{1,3,4} and greater cost-effectiveness.⁵ Risk reductions in this group include a 32% decrease in nonfatal reinfarction, 36% decrease in mortality,³ 300% reduced risk for repeat coronary artery bypass graft (CABG),⁶ and a decreased risk for restenosis after percutaneous transluminal coronary angioplasty from 55% to 38%.⁷

In this study, we used an intensive intervention, which is the gold standard for smoking cessation among inpatients. When tested in the United States, this intervention resulted in the highest rates of 1-year confirmed cessation reported in the literature.⁸ The intervention involves 45–60 minutes of bedside education and counselling during hospital stay followed by 7 nurse-initiated telephone counselling sessions after discharge.⁹ US trials have reported 1-year confirmed cessation rates of 61% for this intensive intervention compared to 32% for a brief intervention when tested as a stand-alone program.¹⁰ When tested as part of a rehabilitation program for multiple cardiac risk factors, the cessation rates were 70% and 53%, respectively.¹¹ Despite the success of this approach among cardiac patients, interventions for smoking cessation in inpatients have not been widely adopted in Canada.

In this randomized clinical trial, we investigated the efficacy of a minimal intervention and an intensive intervention for smoking cessation among patients admitted to hospital because of acute myocardial infarction or for CABG.

Methods

Setting and participants

The setting was 4 cardiac units in a large urban hospital in western Canada. We considered eligible patients to be those who were 18 years of age or older, used tobacco in the month before admission, had a minimum projected hospital stay of 36 hours (to allow time for the intervention), were willing to be randomly assigned to an intervention and had telephone access to receive counselling after discharge. We excluded patients who were pregnant, involved in a concurrent trial for tobacco cessation, medically unstable (as determined by a physician), lived in an institution without telephone access,

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Interventions for smoking cessation are underused in cardiac units in Canada,¹ even though coronary artery disease accounts for a large proportion of hospital admissions among adults aged 45 or more years.² Compared with the use of other secondary prevention and management measures (e.g., statins, acetylsalicylic acid, β -blockers and angiotensin-converting-enzyme inhibitors), the use of

could not speak English or had trouble communicating, had a history of substance abuse or psychiatric disorders, or for whom the patient's physicians refused to allow participation.

The Conjoint Health Research Ethics board of the University of Calgary provided ethics approval for this randomized clinical trial.

Procedure

Over a 15-month period beginning in December 1999, the research nurse asked all patients admitted to each of the 4 cardiac units if they had used tobacco in the month before admission. She reviewed the medical charts of smokers for eligibility, approached medically stable patients at the bedside, described the study, obtained informed consent and collected baseline data. She opened the randomization envelope and informed the patients of intervention assignment (intensive or minimal). We developed the randomization code using a computer random-number generator to select random permuted blocks of 10. Randomization was stratified by acute MI and CABG to ensure equal numbers in each intervention group.

Minimal intervention

The research nurse advised patients to quit smoking by personalizing the message to each patient's medical conditions. The nurse reviewed 2 pamphlets (how to quit and where to find help quitting) with the patient, and she put a note in each patient's chart to ask the attending physician to deliver a scripted nonsmoking message¹² at the bedside during the patient's hospital stay. Pharmacotherapy was not part of the study. However, pharmacotherapy was introduced as an aid to cessation and was available through the hospital formulary during the patient's hospital stay if the patient requested it and a physician ordered it. The research nurse explained how to use the medications to patients who were interested.

Intensive intervention

Patients in this group received the minimal intervention plus 45–60 minutes of bedside education and counselling, take-home materials (video, workbook, audiotape) and 7 telephone counselling sessions initiated by the research nurse (2, 7, 14, 21, 30, 45 and 60 days after discharge). Education covered the patient's personalized risks associated with smoking and the benefits of quitting, as well as withdrawal, weight gain and the benefits of making the home smoke-free. Counselling was based on Marlatt and Gordon's relapse prevention model.¹³ Patients rated their confidence to remain smoke-free in 14 high-risk situations,¹⁴ and they developed behavioural, cognitive and social support strategies to remain smoke-free in situations for which they had less than 70% confidence. Telephone counselling, which was designed to last 5–10 minutes per call,¹⁵ focused on the prevention of relapse (developing cognitive, behavioural and social support strategies for situations identified as high risk for relapse).

Follow-up after discharge

A research assistant who had no prior contact with the participants called each participant at 3, 6 and 12 months after dis-

charge to assess the participant's use of tobacco in the previous 7 days. The assistant was blinded to the intervention assignment by not having any information about the patients, except for their name, scheduled callback date and telephone number (the intervention was not known). During the 12-month follow-up call, the research assistant asked all patients who reported not using tobacco to provide the name and contact number of a family member or friend to provide proxy corroboration of their tobacco status. The assistant then called the friend or family member and asked if the patient had smoked or used tobacco in the last 7 days.

Measures

We collected baseline sociodemographic data, including age, education, employment status, marital status, ethnic background, sex, weekly alcohol consumption, whether patients lived alone or with a smoker, social support to quit tobacco, and the degree of restrictions on tobacco use at home and work. Medical information included history of acute MI, CABG, percutaneous transluminal coronary angioplasty, peripheral vascular disease, chronic obstructive pulmonary disease, diabetes, number of weeks of stable angina, hospital admissions in the previous year, length of the current hospital stay, and discharge diagnosis based on the International Classification of Disease (ninth revision [ICD-9]) codes.¹⁶

We collected information on the history of tobacco use, including the amount and number of years smoked, number of quit attempts, tobacco addictions (5-item modified Fagerstrom Tolerance Questionnaire¹⁷), and previous use of pharmacotherapy, as well as in-hospital withdrawal and difficulty quitting while in hospital. Psychosocial information included single-item screens of the patient's confidence to quit (0%–100% confidence), intention to quit (1–7, with 7 being full intention), depressed mood (0 [not at all] to 8 [very severely depressed]), and beliefs about whether they could avoid health problems by quitting (1 [very likely] to 4 [very unlikely]), whether tobacco was harming their health, and whether it was worth quitting after 20 years of using tobacco (1 [strongly agree] to [4 strongly disagree]¹⁸).

Primary outcome

Our primary outcome was smoking status at 3, 6 and 12 months after discharge. We measured smoking status using the National Heart, Lung and Blood Institute's¹⁹ consensus-conference definition of self-reported 7-day point prevalence of abstinence (not even a puff for a minimum of 7 consecutive days before the assessment) and long-term (continuous) abstinence, which was measured by self-reported 7-day point-prevalence at 3, 6 and 12 months.

Although self-reported tobacco status is a valid measure,^{20,21} we used proxy confirmation as a conservative fidelity check of abstinence at 12 months. Proxy corroboration results in similar abstinence rates to carbon monoxide confirmation of tobacco rates.^{22,23} In this trial, it was more feasible to use a proxy measure than to ask patients to return to hospital to provide a sample for biochemical confirmation because patients resided not only in the hospital community but also in outlying rural areas.

Data analyses

We assumed that the 12-month confirmed abstinence would be 30% in the minimal intervention group (based on the Stanford study¹⁰); thus, 136 participants per group were needed to give an 80% probability of detecting a clinically significant 10% increase in abstinence rates with the intensive intervention ($\alpha = 0.05$, 1 tailed).

We compared the baseline characteristics between the intervention groups using χ^2 tests for categorical and dichotomous variables and t tests for continuous variables. Although statistical testing for baseline differences is discouraged by some,²⁴ others maintain that baseline differences can occur between treatment groups, even with adequate randomization and allocation concealment.²⁵ Thus, the differences should be checked to ensure that the results of this trial and future systematic reviews and meta-analyses that include this trial are not biased.²⁶

For outcomes related to tobacco status, we used hierarchical logistic regression to test for the main effects of the intervention (intensive v. minimal) and the reason for admission to hospital (CABG v. acute MI) and the interaction between the intervention and the reason for admission. Odds ratios (ORs) with 95% confidence intervals (CIs), derived from the last statistically significant step in the logistic analyses, were used to determine the significance of the main effects and the interaction. We excluded from the analyses participants who had died. Those who had dropped out or for whom cessation data were not available were considered smokers for the time points at which their data were missing.

Our secondary analyses included a hierarchical logistic regression analysis to test for the effects of the intervention, pharmacotherapy and the interaction between the intervention and pharmacotherapy on 12-month abstinence. We also performed logistic regression analysis to determine predictors of 12-month

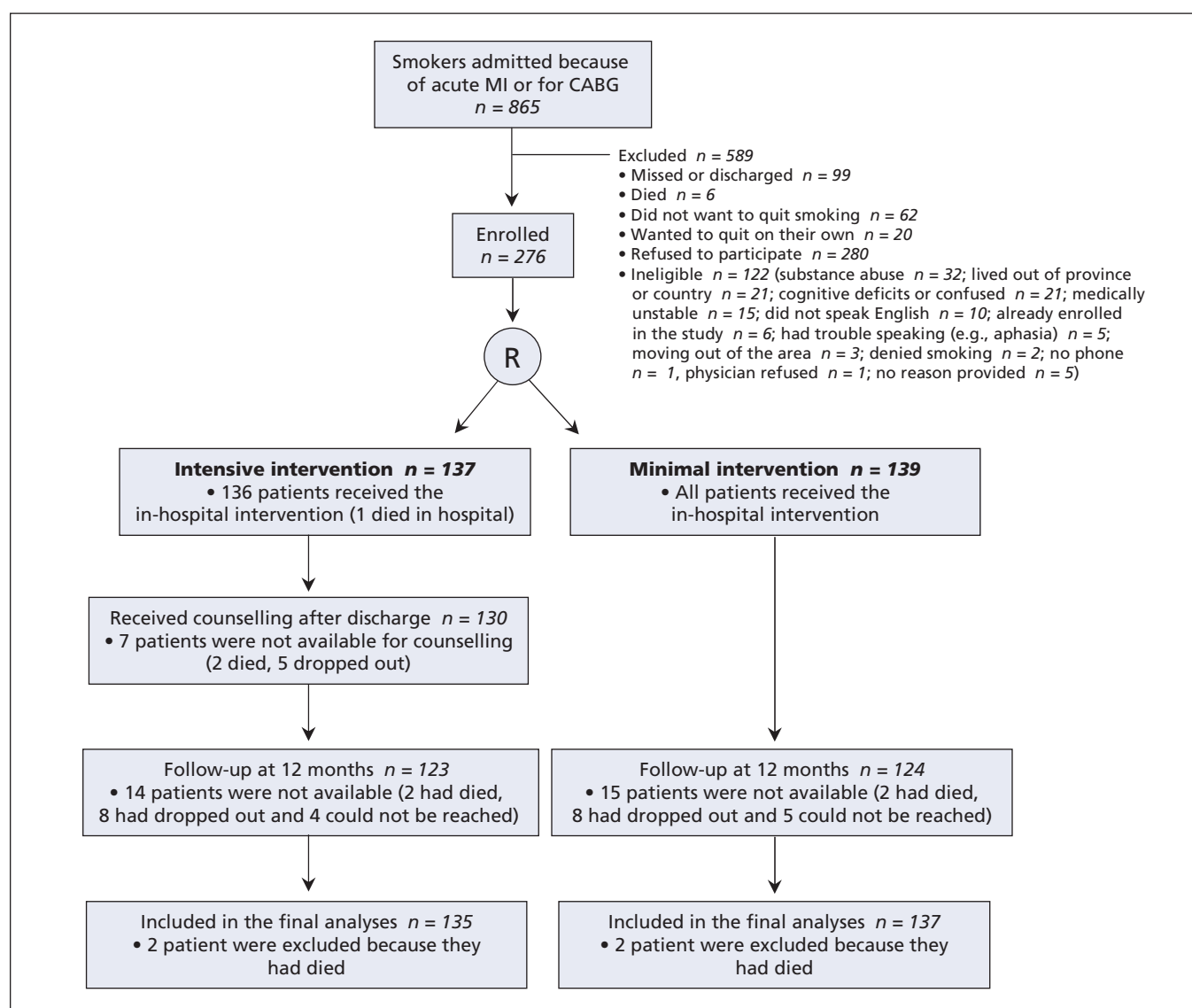


Figure 1: Patient enrollment, allocation, intervention completion and follow-up. Note: CABG = coronary artery bypass graft, MI = myocardial infarction.

cessation, while adhering to conventions to prevent over-fitting the prediction model to the sample.²⁷ The predictors included in the analysis were age, sex, education, admission for CABG or acute MI, history of acute MI, addiction, confidence to quit tobacco, restrictions on indoor tobacco use at home, depression, use of alcohol, and whether the patient had quit tobacco for at least 1 week in the year before hospital admission.

Results

Patient enrollment and flow through the trial

Recruitment began in December 1999, and follow-up ended in March 2003. Of the 10 336 admissions to the 4 cardiac units, 19% were because of acute MI ($n = 1921$) and 14% were for CABG ($n = 1425$). Of the patients with acute MI, 34% ($n = 654$) were smokers, and 15% of the patients admitted for CABG ($n = 211$) were smokers. The overall smoking prevalence rate was 26% (865/3346). Of the patients admitted because of acute MI or for CABG who smoked, 32% were enrolled (276/865) in the study (Figure 1).

All of the patients that were randomly assigned to the minimal intervention and all but 1 of the patients assigned to the intensive intervention received the in-hospital intervention. Of the patients in the intensive intervention, 95% (130/137) received the postdischarge intervention. On average, 93% of patients were available per call, 5% were not reached, and 2% were not called because the research nurse was absent, on vacation or missed a call. Patients received an average of 6.56 (standard deviation 0.8) calls. At the end of the 12-month period, 4 (1%) patients had died, 16 (6%) had dropped out of the study and 9 (3%) were not reached for the final follow-up (i.e., phone line busy, no answer, answering machine, messages not returned).

Participant characteristics

Stratified randomization resulted in equal numbers of CABG and acute MI patients assigned to each intervention group (Table 1). Nine patients did not have an ICD-9 discharge diagnosis code of CABG or acute MI, although they had been admitted for acute MI. There were no significant differences between the groups for medical history (Table 1) or baseline variables (Table 2).

Table 1: Characteristics of patients admitted to hospital because of myocardial infarction or for coronary artery bypass grafting who received a minimal or intensive intervention for smoking cessation

Characteristic	Intensive intervention		Minimal intervention	
	n/N*	% of patients*	n/N*	% of patients*
Hospital stay, d, mean (SD), range	9 (6)	1–36	9 (7)	2–59
Discharge diagnosis†				
CABG‡	27/137	20	31/139	22
CABG and MI§	16/137	12	15/139	11
MI¶	41/137	30	41/139	30
MI and PTCA**	49/137	36	47/139	34
Other				
PTCA††	2/137	2	2/139	1
Coronary artery disease‡‡	2/137	2	3/139	2
Medical history				
Previous MI	22/130	17	27/137	20
Previous CABG	5/134	4	3/137	2
Previous PTCA	12/133	9	18/137	13
Chronic obstructive pulmonary disease	2/133	2	5/129	4
Peripheral vascular disease	4/132	3	8/136	6
Unstable angina in the previous week	113/130	87	104/128	81
Diabetes	23/131	18	24/138	17

Note: CABG = coronary artery bypass graft, MI = myocardial infarction, PTCA = percutaneous transluminal coronary angioplasty, SD = standard deviation.

*Unless otherwise stated.

†Based on ICD-9 codes.¹⁵

‡ICD-9 codes 36.10–36.14.

§ICD-9 codes 36.10–36.14 (CABG) and ICD-9 codes 410.0–410.9 (MI).

¶ICD-9 codes 410.0–410.9.

**ICD-9 codes 410.0–410.9 (MI) and ICD-9 code 36 (PTCA).

††ICD-9 code 36.

‡‡ICD-9 codes 414.0–414.9.

Self-reported abstinence at 3, 6 and 12 months

More patients in the intensive intervention than in the minimal intervention reported not smoking at 3 months ($p = 0.009$), 6 months ($p = 0.003$) and 12 months ($p = 0.007$) (Table 3). The odds of quitting were 2 times greater for patients who received the intensive intervention compared with the minimal intervention at 3, 6 and 12 months (Table 3). The reason for admission to hospital (CABG v. acute MI) or the interaction between the intervention and reason for admission did not contribute significantly to the variance in cessation at any follow-up time.

Confirmation of self-reported abstinence

Of the patients who reported not smoking after 12 months, 16% (23/147) did not provide proxy information to allow us to confirm their smoking status. These patients were considered smokers in this analysis. Of the patients who provided proxy information (84%, 124/147), 3 were reported by a friend or family member to have smoked during the past 7 day (2 in the minimal intervention group, 1 in the intensive intervention group). These 3 patients were considered smokers in this analysis.

More patients in the intensive intervention than in the minimal intervention were confirmed nonsmokers at 12

months ($p = 0.002$) (Table 3). There was no significant effect of reason for admission to hospital (CABG v. acute MI) or significant interaction between the intervention and the reason for admission.

Continuous abstinence at 3, 6 and 12 months

The intervention ($p = 0.004$) and the reason for hospital admission (CABG v. acute MI) ($p = 0.04$) were significant predictors of continuous abstinence. The interaction between the intervention and having CABG or acute MI was not significant ($p = 0.24$). Patients who received the intensive intervention had significantly higher rates of continuous abstinence than those who received the minimal intervention (57% [77/135] v. 39% [54/137]; OR 2.1, 95% CI 1.3–3.4, $p = 0.003$). Patients admitted to hospital for CABG had significantly higher rates of continuous abstinence than those admitted because of acute MI (57% [50/88] v. 44% [81/184]; OR 1.7, 95% CI 1.0–2.9, $p = 0.038$; Table 4).

Pharmacotherapy

Although pharmacotherapy was not part of either intervention, it was used by 34% of patients in both groups (minimal intervention: 40/118 patients; intensive intervention: 40/116 patients [data were missing for 19 patients in each group]). Both the intervention and the use of pharmacotherapy were predictors of abstinence ($p = 0.001$); the interaction between

the intervention and the use of pharmacotherapy was not ($p = 0.26$). Patients who received the intensive intervention had significantly higher odds of being abstinent at 12 months than those who received the minimal intervention (69% [80/116] v. 48% [56/118], OR 2.7, 95% CI 1.5–4.8). In both interventions, patients who used pharmacotherapy had significantly lower odds of being abstinent at 12 months (39% [31/80] v. 68% [105/154], OR 0.3, 95% CI 0.2–0.5; Table 4).

Predictors of 12-month abstinence

Twenty-four patients were missing data for at least 1 of the predictor variables and were excluded from the analyses, leaving a sample size of 248 patients. Significant predictors of the point-prevalence of abstinence at 12 months included receiving the intensive (v. minimal) intervention (OR 2.12, 95% CI 1.2–3.7), having no history (v. having a history) of acute MI before the current admission (OR 2.94, 95% CI 1.3–6.5), having a postsecondary education (v. having a high school education or less) (OR 2.34, 95% CI 1.3–4.1) and having at least some smoking restrictions at home (v. no restrictions) (OR 1.96, 95% CI 1.1–3.5).

Interpretation

More patients in the intensive intervention than in the minimal intervention were abstinent at 1 year (absolute increase of

Table 2: Demographic characteristics and smoking history of patients admitted to hospital because of myocardial infarction or for coronary artery bypass grafting who received a minimal or intensive intervention for smoking cessation

Characteristic	Intensive intervention		Minimal intervention	
	n/N*	% of patients*	n/N*	% of patients*
Age, yr, mean (SD), range	54 (10)	35–80	54 (10)	27–79
Male	113/137	82	115/139	83
White	129/137	94	128/138	93
Married or common law	107/137	78	105/139	76
High school education or less	72/137	53	77/139	55
Employed	103/137	75	99/139	71
Live alone	33/137	24	32/139	23
Severity of tobacco addiction,† mean (SD), range	14.1 (4.0)	5–24	14.6 (4.5)	7–25
No. of cigarettes per day, mean (SD), mode; range	22 (11)	25; 3–62	21 (12)	25; 1–60
No. of years smoked, mean (SD), range	36 (10)	10–60	36 (12)	10–68
Ever attempted to quit	114/137	83	124/139	89
Quit for 1 week in the previous year	30/114	26	35/124	28
Confidence to quit,‡ mean (SD), range	84 (20)	0–100	84 (18)	40–100
Intention to quit,§ mean (SD), range	6.8 (0.6)	3–7	6.8 (0.6)	4–7
Depression, mean (SD), range**	0.94 (2.0)	0–8	1.04 (2.0)	0–8
No. of drinks per week,†† mean (SD), range	2 (4)	0–20	3 (4)	0–21
At least some smoking restrictions at home	77/137	56	76/139	55

Note: SD = standard deviation.

*Unless stated otherwise.

†Modified Fagerstrom Tolerance Index¹⁶ scored from 5 to 25 (low to severe addiction).

‡Measured on a 1-item screen, 0% (no confidence) to 100% (completely confident).

§Measured on a 7-point 1-item screen, 1 (no intention to quit) to 7 (full intention).

**Measured on a 1-item screen, 0 (not at all depressed) to 8 (severely depressed).

††Presented only for those who reported drinking (intensive intervention $n = 96$, minimal intervention $n = 96$).

19%). The odds of quitting smoking were 2 times greater for those in the intensive intervention. The unique contributions of this study include significantly higher rates of continuous abstinence for patients admitted to hospital for CABG than for acute MI, significantly lower rates of abstinence among patients who used pharmacotherapy regardless of the intervention group (which is a finding consistent with general hospital patients)²⁸ and real-time tracking of the prevalence of tobacco use among patients admitted for acute MI or CABG. The prevalence of tobacco use was higher for patients with acute MI (34%) than the provincial average of smoking prevalence (22%–24%),²⁹ which is an important consideration for case-load estimation. In addition to receiving the intensive intervention, the absence of a previous acute MI and having a postsecondary education and at least some restrictions on smoking at home contributed to successful long-term cessation of tobacco use.

The rates of confirmed long-term abstinence observed in this trial are among the highest rates reported in cardiac populations and are among the highest reported absolute differences between minimal and intensive interventions.⁸ Our results suggest that intensive counselling provided during the hospital stay is more effective than a stepped-care approach that provides intensive counselling only after a patient has relapsed.³⁰ By significantly increasing abstinence among cardiac patients, inpatient programs for smoking cessation have the potential to produce sizeable reductions in cardiac events^{1,3,4,6,7} and hospital costs.^{31–34}

In our study, slightly less than half of the identified smokers did not want to quit smoking or refused to participate. Having a full-time nurse to systematically provide the intensive intervention could help to stress to patients the risk of disease and the importance of quitting, as well as encourage patients to at least try to quit or move them

closer to contemplating quitting. The minimal intervention (advice and pamphlets) could also be delivered to these patients as a noninteractive intervention, although resources would need to be taken into consideration.

Given that the primary aim of our trial was to establish the efficacy of the intervention, some exclusion criteria were necessary; this limits the generalizability of the findings. Most notably, cardiac patients with substance abuse or psychiatric comorbidities, or both, were excluded. These patients often require services beyond those offered by a general smoking-cessation program and beyond what the counsellors are trained to deliver. It is difficult to design cessation programs to take into account various cognitive and social deficits.³⁵ Among psychiatric patients, smoking cessation may increase the levels of some psychiatric medications in the blood, exacerbate symptoms and result in problematic adverse effects such as anxiety and depression;^{36–38} the latter is an independent risk factor for heart disease.³⁹

Fifteen years ago, routine smoking-cessation interventions for cardiac patients in hospital were deemed an “idea whose time has come,”⁴⁰ but the interventions have not been widely adopted. The current trial contributes to the international evidence base and provides support to suggest that future research and practice should focus on dissemination of intensive interventions for smoking cessation into standard hospital practice for cardiac patients. The potential contributions to health and health care costs are substantial.

Table 3: Point prevalence and confirmed rates of abstinence after receipt of a minimal or intensive intervention for smoking cessation

Abstinence	Intervention; no. (%) of patients		Difference, %	p value	OR (95%CI)
	Intensive n = 135	Minimal n = 137			
Self-reported					
3 months	102 (76)	83 (61)	15	0.009	2.0 (1.2–3.4)
6 months	90 (67)	67 (49)	18	0.003	2.0 (1.3–3.4)
12 months	84 (62)	63 (46)	16	0.007	2.0 (1.2–3.1)
Confirmed*					
12 months	73 (54)	48 (35)	19	0.002	2.0 (1.3–3.6)

Note: OR = odds ratio, CI = confidence interval.

*Patients who reported being abstinent at 12 months were asked to provide the name and phone number of a friend or relative to confirm their tobacco status. The research assistant called the friend of family member and asked if the patient had smoked or used tobacco in the last 7 days.

Table 4: Smoking abstinence 12 months after receipt of a minimal or intensive intervention for smoking cessation among patients admitted to hospital for acute myocardial infarction or coronary artery bypass grafting

Abstinence at 12 mo	Intensive intervention		Minimal intervention		Total	
	n/N	%	n/N	%	n/N	%
Pharmacotherapy*†						
Used	22/40	55	9/40	22	31/80	39
Not used	58/76	76	47/78	60	105/154	68
Total	80/116	69	56/118	48		
Reason for admission‡						
CABG	30/42	71	20/46	43	50/88	57
Acute MI	47/93	50	34/91	37	81/184	44
Total	77/135	57	54/137	39		

Note: CABG = coronary artery bypass graft, MI = myocardial infarction.

*Data about the use of pharmacotherapy data were missing for 19 patients in each group; these patients were omitted from this analysis.

†Abstinence rates for pharmacotherapy are 7-day point-prevalence confirmed by proxy.

‡Abstinence rates by reason for admission are 12-month continuous abstinence.

This article has been peer reviewed.

Competing interests: Patricia Smith received travel assistance from Pfizer to attend the Global Healthcare Alliance for Treatment of Tobacco Dependence in November 2008. Pfizer manufactures a nicotine-replacement product. None declared for Ellen Burgess.

Contributors: Both Patricia Smith and Ellen Burgess contributed to the conception and design of the study. Patricia Smith designed the data collection tools, oversaw the fidelity of data collection for the CONSORT diagram and data entry, and was responsible for the data analysis and interpretation. She also drafted the article and revised the various iterations. Ellen Burgess was responsible for project management and fidelity of intervention implementation, data collection, interpretation of the data and revisions of the draft manuscript and its iterations. Both authors gave final approval of the version to be published.

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